REMARKS

Claims 1-16 have been rejected. No claims have been allowed. Claims 1-3, 6, 7, 10 and 12-16 are currently amended. Claims 4, 5, 8, 9 and 11 are cancelled. Claims 1-3, 6, 7, 10 and 12-16 remain pending in the application.

Claim 1 has been amended to add structural limitations to the sampling/analysis member used to assay for an analyte of interest in a sample. Claim 1 has been amended to claim a sampling/analysis member which is used to assay for an analyte of interest in a sample comprising: (a) a sampling wand having a sampling swab for collecting the sample of the analyte of interest; and (b) an analysis structure for receiving the sample of the analyte of interest rinsed from the sampling swab and for retaining the analyte for the relatively rapid detection of the presence of the analyte of interest in the sample, the analysis structure having a reagent disc comprising a porous, non-fibrous absorbent polymeric material onto which a reactant system has been loaded by contacting a solution of the reactant system in a solvent with the polymeric material and removing the solvent from the polymeric material. The porous polymeric material of the reagent disc provides a stable environment on which a reactant system can be stored for extended periods. In addition,

the porosity of the polymeric material provides a large internal surface area on which to dry the reactant system which eliminates the need for lyophilization (paragraph 0080 in the specification). Since the reactant system is dried upon a large internal surface area, upon contact with a sample solution the reactants readily achieve rehydration and almost instantaneous mixing. All other claims depend upon Claim 1 and therefore, incorporate these limitations. Support for a sampling wand 17 having a sampling swab 27 is found at paragraph 0052 in the specification. Support for an analysis structure 30 having a reagent disc 48 is found at paragraph 0051 in the specification.

Claim Rejections

(1.) Claims 1-5 and 9-16 were rejected under 35 U.S.C. §102(a) as being clearly anticipated by Applicant's admission of the prior art.

According to M.P.E.P. §2131 a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *See Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim.

Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Applicants teach at paragraph 0077 in the specification of a known, commercially available material (Merocel® CF50 polymeric material) which is a preferred porous, non-fibrous absorbent polymeric material for the reagent disc. While such examples of polymeric materials are known in the art, applicants are first to teach a sampling/analysis member having a reagent disc with a reactant system loaded onto the polymeric material and having the reactant system solvent removed from the reagent disc. Applicants are the first to teach the use of porous, non-fibrous absorbent polymeric materials as a reagent disc onto which to load chemiluminescent reactants. Applicants teach that aqueous solutions of luciferin-luciferase at concentrations suitable for typical assay procedures are relatively unstable and cannot be used more than a day after preparation without significant loss of emission intensity, and then only after a recalibration of the emission signal as a function of an ATP standard (paragraph 0080 in the specification). This is true of any enzymatic assay, since by nature enzymes are relatively unstable. The recognized prior art solution to this problem of stability is to prepare the mixture in a lyophilized form to be coated on

the inner surface of the reaction vessel. The prior art does not teach loading a reactant system onto a reagent disc comprising a porous polymeric material and removing the solvent from the polymeric material.

The present invention is directed to the relatively rapid detection of the presence of an analyte of interest (paragraph 0041 in the specification). In addition to solving the problem with stability, the polymeric material provides for more readily achieved rehydration of the reactant system once the reagent disc is in contact with the sample solution. The relatively large internal surface area of the polymeric material provides for the almost instantaneous mixing of the sample solution with the dried reactants in the reagent disc (paragraph 0080 in the specification). The prior art does not teach the use of polymeric materials as reagent discs to speed the rehydration and mixing of the sample solution with reactants which have been dried to increase stability. Therefore, in light of these amendments, the Claims are patentable over the prior art. Reconsideration of the rejection is requested.

(2.) Claims 6-8 were rejected under 35 U.S.C. § 103(a) as as being anticipated by Applicant's admission of the prior art.

To establish a *prima facie* case of obviousness, three criteria must be met, as found in M.P.E.P. §2143. There must be first some suggestion or motivation to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all of the claim limitations to establish *prima facie* obviousness of a claimed invention. *In re Royka*, 490 F.2d 981,180 USPQ 580 (CCPA 1974). This teaching or suggestion to make the claimed combination must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). The prior art does not teach the use of polymeric materials as reagent discs on which a reactant system is directly loaded and dried for increased stability of the system. The prior art does not teach the use of polymeric materials as reagent discs to speed the rehydration and mixing of the sample solution with dried reactants. There is no teaching or suggestion of all of the claim limitations outside of applicants' disclosure. Therefore, no *prima facie* case of obviousness can be established. In light of these amendments, the Claims are

patentable over the prior art materials. Reconsideration of the rejection is requested.

(3.) Claims 1-16 were rejected under 35 U.S.C. §102(b) as being anticipated by Rosenblatt (U.S. Patent No. 4,098,728).

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Rosenblatt teaches a hydrophilic medical sponge comprising polyvinyl alcohol with high fluid holding capacity. Rosenblatt further teaches the use of such material as a diagnostic swab. Rosenblatt does not describe, either expressly or inherently, a reagent disc wherein the reactant system has been loaded onto the reagent disc by contacting a solution of the reactant system in an appropriate solvent with the polymeric material and removing the solvent from the polymeric material. Since Rosenblatt does not describe these limitations, anticipation of the claimed invention cannot be established. In light of these amendments, the Claims are patentable over Rosenblatt. Reconsideration of the rejection is requested.

The cited references do not teach all of the elements of the present invention. Therefore, in light of the above, it is now believed that Claims 1-3, 6, 7, 10 and 12-16 are patentable and in condition suitable for allowance. Applicants respectfully requests that a timely Notice of Allowance be issued in this case.

Enclosed is U.S. Patent No. 5,726,062 to Numa *et al.* generally relating to sampling kits which has recently come to our attention.

Respectfully,

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